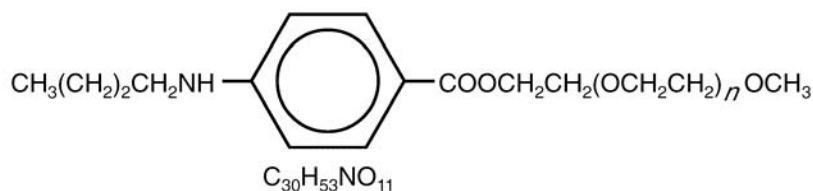


BENZONATATE - benzonatate capsule

Cadila Healthcare Limited

DESCRIPTION

Benzonatate capsules, USP, a non-narcotic oral antitussive agent, is 2,5,8,11,14,17,20,23,26-nonaoxaocacosan-28-yl *p*-(butylamino) benzoate; with molecular weight of 603.7.



Each benzonatate capsule for oral administration contains 100 mg or 200 mg of benzonatate. In addition, each capsule also contains the following inactive ingredients: gelatin, glycerin, noncrystallising sorbitol solution, methylparaben, propylparaben and purified water.

CLINICAL PHARMACOLOGY

Benzonatate capsules act peripherally by anesthetizing the stretch receptors located in the respiratory passages, lungs, and pleura by dampening their activity and thereby reducing the cough reflex at its source. It begins to act within 15 to 20 minutes and its effect lasts for 3 to 8 hours. Benzonatate capsules have no inhibitory effect on the respiratory center in recommended dosage.

INDICATIONS AND USAGE

Benzonatate capsules are indicated for the symptomatic relief of cough.

CONTRAINDICATIONS

Hypersensitivity to benzonatate or related compounds.

WARNINGS

Severe hypersensitivity reactions (including bronchospasm, laryngospasm and cardiovascular collapse) have been reported which are possibly related to local anesthesia from sucking or chewing the capsule instead of swallowing it. Severe reactions have required intervention with vasopressor agents and supportive measures.

Isolated instances of bizarre behavior, including mental confusion and visual hallucinations, have also been reported in patients taking benzonatate capsules in combination with other prescribed drugs.

PRECAUTIONS

Benzonatate is chemically related to anesthetic agents of para-aminobenzoic acid class (e.g., procaine; tetracaine) and has been associated with adverse CNS effects possibly related to a prior sensitivity to related agents or interaction with concomitant medication.

Information for patients

Release of benzonatate from the capsule in the mouth can produce a temporary local anesthesia of the oral mucosa and choking could occur. Therefore, the capsules should be swallowed without chewing.

Usage in Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with benzonatate capsules. It is also not known whether benzonatate capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzonatate capsules should be given to pregnant woman only if clearly needed.

Nursing mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when benzonatate capsules are administered to a nursing woman.

Carcinogenesis, mutagenesis, impairment of fertility

Carcinogenicity, mutagenicity, and reproduction studies have not been conducted with benzonatate capsules.

Pediatric Use

Safety and effectiveness in children below the age of 10 have not been established.

ADVERSE REACTIONS

Potential Adverse Reactions to Benzonatate Capsules may include: Hypersensitivity reactions including bronchospasm, laryngospasm, cardiovascular collapse possibly related to local anesthesia from chewing or sucking the capsule.

CNS

Sedation; headache; dizziness; mental confusion; visual hallucinations.

GI

Constipation; nausea; GI upset.

Dermatologic

Pruritus; skin eruptions.

Other

Nasal congestion; sensation of burning in the eyes; vague "chilly" sensation; numbness of the chest; hypersensitivity.

Rare instances of deliberate or accidental overdose have resulted in death.

OVERDOSAGE

Overdose may result in death.

The drug is chemically related to tetracaine and other topical anesthetics and shares various aspects of their pharmacology and toxicology. Drugs of this type are generally absorbed after ingestion.

Signs and Symptoms

If capsules are chewed or dissolved in the mouth, oropharyngeal anesthesia will develop rapidly. CNS stimulation may cause restlessness and tremors which may proceed to clonic convulsions followed by profound CNS depression.

Treatment

Evacuate gastric contents and administer copious amounts of activated charcoal slurry. Even in the conscious patient, cough and gag reflexes may be so depressed as to necessitate special attention to protection against aspiration of gastric contents and orally administered materials. Convulsions should be treated with a short-acting barbiturate given intravenously and carefully titrated for the smallest effective dosage. Intensive support of respiration and cardiovascular-renal function is an essential feature of the treatment of severe intoxication from overdose.

Do not use CNS stimulants.

DOSAGE AND ADMINISTRATION

Adults and Children over 10: Usual dose is one 100 mg or 200 mg capsule t.i.d. as required. If necessary, up to 600 mg daily may be given.

HOW SUPPLIED

Benzonatate capsules USP, 100 mg are light yellow-colored, round-shaped soft gelatin capsules, imprinted with "Z" containing pale yellow-colored clear viscous liquid and are supplied as follows:

NDC 68382-247-01 in bottle of 100 capsules

NDC 68382-247-05 in bottle of 500 capsules

Benzonatate capsules USP, 200 mg are light yellow-colored, round-shaped soft gelatin capsules, imprinted with "β" containing pale yellow-colored clear viscous liquid and are supplied as follows:

NDC 68382-248-01 in bottle of 100 capsules

Store at 20° - 25°C (68° - 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by:

Cadila Healthcare Ltd.

Ahmedabad, India.

Distributed by:

Zydus Pharmaceuticals USA Inc.

Princeton, NJ 08540

Rev.: 12/09

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 68382-247-01 in bottle of 100 capsules

Benzonatate Capsules USP, 100 mg

R_x only
100 capsules
ZYDUS



NDC 68382-248-01 in bottle of 100 capsules
Benzonatate Capsules USP, 200 mg
R_x only
100 capsules
ZYDUS

